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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,524	08/15/2006	Victor Albert Raul	DC5078 PCT 1	9898

137 7590 02/27/2009

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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
02/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents.admin@dowcorning.com

Office Action Summary	Application No.	Applicant(s)	
	10/589,524	RAUL ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-18 are currently pending. Claims 1-13 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 14-18 are withdrawn from consideration.

Election/Restrictions

Applicants' election of Group II (claims 1-13) in the reply filed on Dec. 8, 2008 is acknowledged. In response to applicant's election, Group I (claims 14-18) is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants have elected Group II with traverse.

The traversal is on the ground(s) that the compounds taught by CYPRIEN (U.S. 5,114,707; Issued May 19, 1992; 4th reference on the IDS submitted by applicant dated Aug. 15, 2006), cited in the restriction requirement, do not teach a silicone polyether. While applicant appears to be correct in this assessment, the instantly claimed method is an obvious variation over the prior art as discussed below. As, such the instantly claimed method cannot be considered a contribution over the prior art and the claims are subject to restriction. The restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The references provided on the information disclosure statement(s) were considered and have been made of record.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is indefinite in the recitation "less than about 20". This phrase is indefinite. See MPEP § 2173.05(b) which states, "In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927

F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 8, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over ULMAN (U.S. 5,607,721, issued March 4, 1997) in view of PORTER (U.S. 5,785,978; Issued Jul. 28, 1998).

1. Ulman discloses a pressure sensitive adhesive (PSA) composition comprising a siloxylated polyether and methods of making the same (abstract). Ulman teaches that due to the presence of the siloxylated polyether component, the adhesive compositions of the invention are especially suitable for delivering hydrophilic bioactive agents to a patient's skin (column 7, lines 11-14; column 7, lines 39-45). Ulman teaches that the adhesive compositions of the invention are prepared by mixing the PSA with the siloxylated polyether (i.e. elements (ii) and (iii) of instant claim 1) (column 6, lines 24-29).

2. Ulman teaches that the bioactive agent can be incorporated into the adhesive composition (column 7, lines 11-14), but does not explicitly define at what stage of mixing that the bioactive agent is added. Therefore, Ulman does not explicitly teach element (i) of instant claim 1. Additionally, Ulman does not explicitly disclose suitable forms of the bioactive agent.

3. However, forming a first composition comprising a hydrophilic drug or excipient and the silicone polyether is one of only a small number of possibilities for the addition order of the components. In addition to the bioactive agent, the compositions of Ulman comprise only two other components; the PSA and the siloxylated polyether. Therefore, the artisan would have but three choices for the mixing order of the hydrophilic drug/excipient. The artisan could either choose to mix the hydrophilic drug/excipient

with: 1) the silicone polyether prior to adding it to the adhesive; 2) the pressure sensitive adhesive prior to adding it to the polyether or 3) the mixture of the PSA and the silicone polyether. As such it would have been *prima facie* obvious to the ordinary artisan to mix the hydrophilic drug/excipient in any of these ways, and it would be routine for the artisan to do so to determine the best mode of dispersing the hydrophilic drug/excipient in the adhesive matrix. Nonetheless, the teachings of Ulman would have guided the artisan to the first of these three options. The distinctive feature of the Ulman compositions is the presence of the hydrophilic siloxylated polyether component (title; abstract), and it is clear from the teachings of Ulman that it is this component that provides suitable compatibility of hydrophilic drugs/excipients (column 7, lines 39-45). Further, Ulman teaches that prior art compositions without such a polyether component are inadequate for the delivery of hydrophilic drugs (column 1, lines 62-64). Thus, the ordinary artisan would reasonably expect greater compatibility of the hydrophilic drug/excipient with the more hydrophilic polyether component (i.e. the well-known principle of like-dissolves-like), and would be motivated to form a pre-composition comprising the hydrophilic drug/excipient and the silicone polyether prior to mixing with the more hydrophobic PSA, which was known from the prior art to be incompatible with such hydrophilic components.

4. Regarding the limitation that the hydrophilic component be in powdered (i.e. solid) form, Ulman does not explicitly disclose suitable forms of the bioactive agent. Therefore, the ordinary artisan would have looked to the literature for guidance as to the form of the incorporated drug. The addition of powdered active agents to silicone

pressure sensitive adhesives was well-known in the art at the time of the invention. For example, Porter discloses adhesives containing active ingredients for transdermal patches (abstract). Porter teaches that a preferable bioactive agent in the adhesive matrix is vitamin C (i.e. a hydrophilic bioactive agent) (column 4, lines 16-17) and that the adhesive is preferably a pressure sensitive adhesive (column 4, lines 28-29). Porter teaches that the active agents (e.g. vitamin C) are applied in powdered form (abstract), which is most preferred because the agents are more highly concentrated than in liquid form (column 5, lines 36-42). Porter exemplifies silicone pressure sensitive adhesives containing powdered vitamin C in powdered form (Example 2.1-2.3).

5. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a hydrophilic drug (i.e. bioactive agent) in solid powdered form per the teachings of Porter. One would have been motivated to do so to produce an adhesive matrix with a highly concentrated active agent. Thus, claim 1 is obvious over Ulman and Porter.

6. Regarding claim 2, it is noted that the term hydrophobic has not been defined in the instant specification. Therefore, the term has been given its ordinary meaning and has been interpreted broadly. PSAs are typically considered to be hydrophobic, as would be recognized by the ordinary artisan, and the PSA components described by Ulman are substantially the same as the PSA components of the instant application, which are deemed hydrophobic (see the abstract and paragraphs [0007] and [0010] of the instant application). For example, Ulman teaches that the use of silicone PSAs are preferred over other types of PSAs (column 1, lines 28-29). The PSAs taught by Ulman

comprise silicone resins of the MQ type that comprise $R_3SiO_{1/2}$ and SiO_4 units and comprise a hydroxyl-terminated (i.e. endblocked) polydiorganosiloxane fluid (abstract; column 2, line 45-67). Ulman teaches that these fluids have a viscosity of 100 to 500,000 centipoise (it is noted that centipoise and centistokes are roughly equivalent, differing only by the specific gravity, which is close to one) (column 3, lines 35-36). Thus, the adhesives of Ulman would be considered hydrophobic by an ordinary artisan and claims 2, 3, 7, and 8 are rendered obvious by Ulman and Porter.

7. Regarding claim 4, Ulman teaches applying the adhesive matrix to a substrate (abstract; column 2, lines 30-31; column 6, lines 28-29, 45, and line 63 to column 7, line 14; claim 3). Thus, claim 4 is obvious over Ulman and Porter.

8. Regarding claim 5, Ulman does not disclose the amounts of hydrophilic drug/excipient to be used in the invention. However, Ulman teaches the amount of drug released from the inventive composition can be controlled (column 2, lines 1-2). It would be routine optimization for the ordinary artisan to adjust the amount of hydrophilic drug/excipient in the composition depending on the intended application of the adhesive, for example the particular patient and/or condition to be treated, the length of time for the treatment, and the particular drug used. Thus, claim 5 is obvious over Ulman and Porter.

9. Regarding claim 10, Ulman teaches that the siloxylated polyether can be any silicone polymer that contains an alkyl wax and polyethylene oxide functionality, such as those represented by the formulae at the top of column 5. These formulae encompass dimethylsiloxy (wherein R^2 is an alkyl radical having 1 carbon) and oxyalkylene

functional siloxy (wherein A is a polyethylene oxide group) repeating units (column 4, line 60 to column 5, line 35). Ulman teaches that the R^2 radicals are preferably methyl (i.e. dimethylsiloxy repeating units) (column 5, line 30). Ulman teaches that the number of repeating units in the polyether can be from 1-70 (column 5, lines 53-55), encompassing the claimed degree of polymerization of less than about 20 (i.e. where there are less than about 20 repeating units per polymer chain). Furthermore, one would be motivated to use a lower molecular weight polyether (i.e. the lower range of Ulman teaching) because Ulman teaches that the siloxylated polyether functions to decrease the dynamic viscosity of the PSA. Since the ordinary artisan would recognize that degree of polymerization is also a measure of molecular weight, which correlates generally with viscosity (i.e. higher MW typically possess greater viscosity), one would recognize the advantages of using a lower MW polyether, for example having a degree of polymerization of less than about 20.

10. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a silicone polyether containing dimethylsiloxy and oxyalkylene repeating units and having a degree of polymerization less than about 20 per the teachings of Ulman. One would have been motivated to do so since Ulman teaches that such polyethers are preferred species of the polyether component and since they function to reduce the viscosity of the PSA, making it easier to spread. Thus, claim 10 is rendered obvious over Ulman and Porter.

11. Regarding claims 12 and 13, it is noted that the term surfactant has not been defined in the instant specification. Therefore the term has been given its plain meaning

and has been interpreted broadly. It is noted that the polyether is used *as* the surfactant in the instant specification and the polyether component is clearly synonymous with the recited surfactant (see paragraphs [0020] and [0030]). Thus, Ulman and Porter read on claims 12 and 13 based on the reasoning applied above (see especially the rejection of claims 1-4).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 6, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulman in view of Porter as applied to claims 1-5, 7, 8, 10, 12, and 13 above, and further in view of KANIOS (U.S. 6,337,086; Jan. 8, 2002).

12. The teachings of Ulman and Porter are presented *supra*. Additionally, Ulman teaches that silicone PSAs known in the art are typically solvent based adhesives, the solvents being employed primarily to reduce the PSAs viscosity prior to coating (column 1, lines 14-19). Ulman teaches that the silicone resin can be dissolved in a solvent such

as benzene, toluene, xylene, heptane, or linear or cylic siloxanes, but does not disclose the amount of solvent in the adhesive matrix of the invention. Ulman does not teach the use of polydiorganosiloxane gums.

13. However, as noted by Ulman, solvent containing PSAs were well known in the art at the time of the invention. For instance, Kanios discloses transdermal drug delivery devices comprising a silicone PSA that comprises a silicone resin and a polydiorganosiloxane silicone fluid (abstract). Kanios teaches the use of an effective amount of an organic solvent such as, *inter alia*, benzene, toluene, xylene, or mixtures thereof, that is inert with respect to the other components of the PSA (column 5, lines 13-15 and 50-54). Kanios teaches that it is preferred to have the PSA compositions in organic solvent solution wherein the organic solvent comprises from 30-70 weight percent of the total mixture of PSA components (column 11, lines 33-38).

14. Kanios further teaches the use of hydroxyl-endblocked polydiorganosiloxane gums, which are polydiorganosiloxanes having viscosities in excess of 1,000,000 cP (column 6, lines 51-54). Kanios teaches that blending endblocked silicone resins with polydiorganosiloxane gums results in a PSA composition having minimal hydroxyl radical content, which can be useful to prepare PSA films for transdermal drug delivery (column 14, line 62 to column 15, line 12). Kanios teaches that the use of solvents is often necessary when using gums in the PSAs (column 10, lines 41-46). Since Ulman does not disclose suitable amounts of solvent in the PSA, the ordinary artisan would look to the literature for guidance on this parameter, and would be motivated to use

values known in the art for similar PSA compositions, such as those taught by Kanios. Thus, claims 6, 9, and 11 are rendered obvious over Ulman, Porter, and Kanios.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 5,607,721

Claims 1-13 are non-provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,607,721 in view of Porter. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '721 claims renders obvious that of the instant claims. While the '721 claims are drawn to a method of coating a silicone PSA onto a substrate, they encompass the step of mixing the instantly claimed adhesive elements, and step (i) of instant claim 1 is obvious as discussed above. Therefore, based on the reasoning applied above '721 and Porter render the instant claims obvious.

Claims 1-13 are directed to an invention not patentably distinct from claims 1-3 of commonly assigned 5,607,721. Specifically, the '721 claims render obvious the instant claims in combination with Porter.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 5,607,721, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643